I U C L I D

Data Set

New Chemical	:	ID: 74-96-4
CAS No.	:	74-96-4
EINECS Name	:	bromoethane
EC No.	:	200-825-8
TSCA Name	:	Ethane, bromo-
Molecular Formula	:	C2H5Br

Producer related part

Company	:	GREAT LAKES CHEMICAL CORPORATION
Creation date	:	18.12.2002

Substance related part

Company	:	GREAT LAKES CHEMICAL CORPORATION
Creation date	:	18.12.2002
Status	:	
Memo	:	
Printing date	:	27.12.2002
Revision date	:	
Date of last update	:	27.12.2002
Number of pages	:	26
Chapter (profile)	:	Chapter: 2, 5
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

2.1 MELTING POINT

Value	:	= -119 °C
Sublimation	:	
Method	:	
Year	:	
GLP	:	
Test substance	:	other TS: Bromoethane
Reliability	:	(2) valid with restrictions DATA QUALITY: Klimisch 2. A reliability code of 2 is assigned to data from recognized reference handbooks.

18.12.2002 (4) (6) (8) (9) (10) (11)

2.2 BOILING POINT

Value	:	= 38.4 °C at
Decomposition	:	
Method	:	
Year	:	
GLP	:	
Test substance	:	other TS: Bromoethane
Reliability	:	(2) valid with restrictions DATA QUALITY: Klimisch 2. A reliability code of 2 is assigned to data from recognized reference handbooks.

18.12.2002 (4) (6) (8) (9) (10) (11)

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Decomposition	:	
Method	:	
Year	:	
GLP	:	
Test substance	:	other TS: Bromoethane
Result	:	475 mm Hg at 25 degrees C
Reliability	:	(2) valid with restrictions DATA QUALITY: Klimisch 2. A reliability code of 2 is assigned to data from recognized reference handbooks.

26.12.2002 (4) (6) (8) (9) (10) (11)

Decomposition	:	
Method	:	
Year	:	
GLP	:	
Test substance	:	other TS: Bromoethane
Result	:	467 mm Hg at 25 degrees C

Reliability : (2) valid with restrictions
DATA QUALITY: Klimisch 2. A reliability code of 2 is assigned to data from recognized reference handbooks.

26.12.2002 (3)

2.5 PARTITION COEFFICIENT

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in : Water
Value : = .91 other: w/w at 20 °C
pH value :
concentration : at °C
Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description :
Stable :

Result : RESULT: 0.91% (w/w) in water @ 20 degrees C (Handbook Data)
Reliability : (2) valid with restrictions
DATA QUALITY: Klimisch 2. A reliability code of 2 is assigned to data from recognized reference handbooks.

26.12.2002 (4) (6) (8) (9) (10)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

5.1.2 ACUTE INHALATION TOXICITY

Type	:	LC50
Value	:	= 4681 ppm
Species	:	rat
Strain	:	Fischer 344
Sex	:	male/female
Number of animals	:	50
Vehicle	:	
Doses	:	0, 659, 1249, 2409, 5171 or 9883 ppm (actual concentrations); equal to 0, 2.9, 5.57, 10.7, 23.1 or 44.1 mg/l. [1mg/l = 224.3 ppm]
Exposure time	:	
Method	:	OECD Guide-line 403 "Acute Inhalation Toxicity"
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane
Method	:	SPECIES/SEX: Fischer 344/N albino rats; males and females 7 weeks old. DOSE LEVEL(s) and NUMBER OF DOSES: Five dose concentrations: 0, 659, 1249, 2409, 5171 or 9883 ppm (actual concentrations); equal to 0, 2.9, 5.57, 10.7, 23.1 or 44.1 mg/l. [1mg/l = 224.3 p pm] NUMBER OF ANIMALS/DOSE: 5 males and 5 females per dose group. Initial body weights for males were 149-161 grams, and for females 119-121 grams. STUDY METHOD: Groups of 5 male and 5 female Fischer 344/N rats were exposed to test material for 4 hours. Temperature was 72-80 degrees F; humidity was 41-73%. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Actual concentrations were determined. Animals were observed continuously during exposure and 3 times a day for 14 days. There were 20 chamber air changes per hour.
Remark	:	Reason: Chamber design, size and exposure method (nose only, full body, etc.) were not described in the report.
Result	:	MEASURED ENDPOINT/INDEX (i.e. LC50, PII): LC50 =4681 ppm. Death occurred on days 2 and 3 at 5171 ppm (females) and 9883 ppm (males/females). RESULTS/OBSERVATIONS: Reactions to vapor concentrations included increased respiration rate, hyperactivity, and incoordination. Late in exposure animals became dyspneic and comatose.
Test substance	:	TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is -119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents.

C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Reliability : (2) valid with restrictions
DATA QUALITY: Study was conducted in accordance with a recognized scientific procedure for analyzing the acute inhalation toxicity of a test material in experimental animals. The study meets contemporary scientific standards and provides sufficient information to support the conclusion that the inhalation LC50 in albino rats is 4681 ppm.

18.12.2002 (6)

Type : LC50
Value : = 27000 ppm
Species : rat
Strain : Sprague-Dawley
Sex : male/female
Number of animals :
Vehicle :
Doses :
Exposure time : 1 hour(s)
Method : other: Pre-dates accepted OECD methods
Year : 1977
GLP :
Test substance : other TS: Bromoethane

Method : SPECIES/SEX: Sprague-Dawley Rats, 200-300 grams; both sexes.

DOSE LEVEL(s) and NUMBER OF DOSES: Number of dose levels not specified.

NUMBER OF ANIMALS/DOSE: Five rats/sex per dose level.

STUDY METHOD: Groups of male and female Sprague-Dawley rats were exposed for 1 hour to concentrations of test material in large desiccators. Chamber concentrations were measured by standard techniques or methods developed in the laboratory. These were checked to give relative SD of 5% or less.

Remark : Reason: This report lacks sufficient details about the test method and protocol, data generated, dose levels used and other specific information, including the purity of the test material.

Result : MEASURED ENDPOINT/INDEX (i.e. LC50, PII): LC50 = 27,000 ppm (25,400-28,700 ppm).

RESULTS/OBSERVATIONS: The only results reported were the LC50 values.

Test substance : TEST MATERIAL: Bromoethane; purity and other information not reported.

Reliability : (4) not assignable
DATA QUALITY: Study was conducted to evaluate the acute toxicity (oral, dermal, inhalation and corrosion characteristics) of a number of organic and inorganic compounds and aqueous solutions. There were 110 materials tested. The method reportedly followed those of Thompson (1947) and Weil (1952) but sufficient details in this particular published report were lacking.

26.12.2002 (1)

Type : LC50
Value : = 2723 ppm
Species : mouse
Strain : B6C3F1
Sex : male/female
Number of animals : 50
Vehicle :

Doses	:	0, 659, 1249, 2409, 5171 or 9883 ppm (actual concentrations); equal to 0, 2.9, 5.57, 10.7, 23.1 or 44.1 mg/l. [1mg/l = 224.3 ppm]
Exposure time	:	
Method	:	OECD Guide-line 403 "Acute Inhalation Toxicity"
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane

Method : SPECIES/SEX: B6C3F1 albino mice; males and females 8-9 weeks old.

DOSE LEVEL(s) and NUMBER OF DOSES: Five dose concentrations: 0, 659, 1249, 2409, 5171 or 9883 ppm (actual concentrations); equal to 0, 2.9, 5.57, 10.7, 23.1 or 44.1 mg/l. [1mg/l = 224.3 ppm]

NUMBER OF ANIMALS/DOSE: 5 males and 5 females per dose group. Initial body weights for males were 24-25 grams, and for females 20-22 grams.

STUDY METHOD: Groups of 5 male and 5 female B6C3F1 mice were exposed to test material for 4 hours. Temperature was 72-80 degrees F; humidity was 41-73%. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Actual concentrations were determined. Animals were observed continuously during exposure and 3 times a day for 14 days. There were 20 chamber air changes per hour.

MEASURED ENDPOINT/INDEX (i.e. LC50, PII): LC50 =2723 ppm. Death occurred on days 1-10 at 1249 ppm (females) and 5171 ppm (males/females).

Remark	:	Reason: Chamber design, size and exposure method (nose only, full body, etc.) were not described in the report.
Result	:	RESULTS/OBSERVATIONS: Reactions to vapor concentrations included increased respiration rate, hyperactivity, and incoordination.
Test substance	:	TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.
Attached document	:	AI2ResultsTable.doc
Reliability	:	(2) valid with restrictions DATA QU ALITY: Study was conducted in accordance with a recognized scientific procedure for analyzing the acute inhalation toxicity of a test material in experimental animals. The study meets contemporary scientific standards and provides sufficient information to support the conclusion that the inhalation LC50 in albino mice is 2723 ppm.

18.12.2002 (6)

Type	:	LC50
Value	:	= 16200 ppm
Species	:	mouse
Strain	:	other: CF-1
Sex	:	male/female
Number of animals	:	
Vehicle	:	
Doses	:	
Exposure time	:	1 hour(s)

Method	:	other: Pre-dates accepted OECD methods
Year	:	1977
GLP	:	
Test substance	:	other TS: bromoethane
Method	:	SPECIES/SEX: CF-1 male mice weighing 22-28 grams. DOSE LEVEL(s) and NUMBER OF DOSES: Number of dose levels not specified. NUMBER OF ANIMALS/DOSE: Five male mice per dose level. STUDY METHOD: Male CF-1 mice were exposed for 1 hour to concentrations of test material in bell jars. Chamber concentrations were measured by standard techniques or methods developed in the laboratory. These were checked to give relative SD of 5% or less.
Remark	:	Reason: This report lacks sufficient details about the test method and protocol, data generated, dose levels used and other specific information, including the purity of the test material.
Result	:	MEASURED ENDPOINT/INDEX (i.e. LC50, PII): LC50 (mice) = 16,200 ppm (15,400-18,600 ppm). RESULTS/OBSERVATIONS: The only results reported were the LC50 values.
Test substance	:	TEST MATERIAL: Bromoethane; purity and other information not reported.
Reliability	:	(4) not assignable DATA QUALITY: Study was conducted to evaluate the acute toxicity (oral, dermal, inhalation and corrosion characteristics) of a number of organic and inorganic compounds and aqueous solutions. There were 110 materials tested. The method reportedly followed those of Thompson (1947) and Weil (1952) but sufficient details in this particular published report were lacking.

26.12.2002 (1)

Type	:	other: Lethality, toxic symptoms and time of onset.
Value	:	
Species	:	guinea pig
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	1,700 ppm to 180,000 ppm
Exposure time	:	
Method	:	other: Pre-dates OECD methods
Year	:	1929
GLP	:	
Test substance	:	other TS: Bromoethane
Method	:	SPECIES/SEX: Guinea pigs (sex and strain not specified). DOSE LEVEL(s) and NUMBER OF DOSES: 1,700 ppm to 180,000 ppm NUMBER OF ANIMALS/DOSE: The number of Guinea Pigs per exposure level varied from 3-6 per dose. The exposure durations were also varied 5 to 810 minutes. There were approximately 52 control animals total from all four chemicals that were tested. STUDY METHOD: Groups guinea pigs were placed in inhalation chambers that had a capacity of 250 cubic feet These were whole body exposures. Also the exposures were "static" in design; that is the test material was introduced into the chamber as a batch followed by mixing. Static exposures have limitations such as loss of test material with consequent decrease in concentration. Also, the volume of the inhalation chamber

decrease in concentration. Also, the volume of the inhalation chamber poses limitations because of oxygen depletion and carbon dioxide and heat build-up. Nonetheless, liquid test material was evaporated by pouring onto a large flat surface inthe chamber. The air was continually stirred with a fan. The starting time for exposure was the time when half the test material had evaporated. For extended exposure times, sampling was repeated at intervals throughout the test. Additional material was added through a tube if the desired concentration had decreased. Additional oxygen was also added when the air content was less than 18 percent. Animals were observed throughout the test for physical signs and symptoms. After the desired exposure, two animals from each group were killed within 2 hours, 2 more within 4 days and 2 after 8 days. These animals were necropsied and some tissues were examined microscopically.

Remark : Reason: Static exposure pattern and test material purity not adequately described.

Result : MEASURED ENDPOINT/INDEX (i.e. LC50, PII):Lethality, toxic symptoms and time of onset were measured throughout the various exposure intervals.

RESULTS/OBSERVATIONS: Concentrations of 100,000 to 180,000 ppm: animals unable to stand after 1 minute; convulsions; unconsciousness and death within 16-19 minutes. Concentrations of 50-60,000 ppm: animals were unsteady within 5-14 minutes; convulsions and death occurred within 98 minutes. No deaths occurred at 60,000 ppm for 10 minutes. Concentration of 24,000 ppm: animals became unsteady, dizzy, and lying on their sides within 13 minutes; no deaths occurred within 10 minutes, but 3 out of 4 died in 1-3 days after a 30 minute exposure; all were dead in 18 hours after 90 minutes of exposure. Concentrations of 10,200-12,000 ppm: no symptoms were observed after 90 minutes; weakness after 270 minutes; however, 1 out of 3 dead in 30 minutes at 10,200 ppm, although no deaths occurred at 12,000 ppm for 55 minutes. One death occurred in 3 days after a 90 minute exposure and all died in 18 hours after 270 minutes of exposure. Concentrations of 6,500-6,700 ppm: No symptoms except weakness after 540 minutes of exposure; 1 death after 180 minutes; all dead in 3 days after 270 minutes of exposure; all pigs dead in 12 hours after 540 minutes, 630 or 810 minutes of exposure. Concentrations of 3,200 ppm: No symptoms. No deaths after 270 minutes of exposure, but all dead in 5 days after 540 minutes of exposure. Concentration of 1,700 ppm: No symptoms after 810 minutes of exposure. 1 died within 1 day following this exposure. Human exposure: 2 male subjects exposed themselves to 6,500-12,000 ppm for 5 minutes. This was irritating to the eyes, produced an oily taste, and vertigo followed by headache.

GROSS NECROPSY: Generally, exposures of 3,200 to 1,700 ppm produced no marked effects when exposure duration was limited to 540 minutes to 5 minutes, respectively. However, when either exposure concentration or time of exposure were increased there were notable pathological findings. For example, animals exposed to 1,700 ppm for 810 minutes displayed hemorrhage in lungs and slightly congested liver, spleen and pancreas. Higher concentrations and durations produced animals with parenchymous degeneration in the liver and kidneys; congestion, hemorrhage, edema and emphysema in lungs; and frequently, petechial hemorrhage in large intestines and gall bladder.

Test substance : TEST MATERIAL: Bromoethane; purity and other information not reported; "good grade commercial product".

Reliability : (3) invalid
DATA QUALITY: Study was conducted to evaluate the acute inhalation toxicity following various exposure concentrations and durations. The study was conducted prior to the introduction of GLP regulations or before test protocols had been standardized. The inhalation method employed a static rather than dynamic exposure pattern. Static exposures introduce test material into the chamber as a batch followed by mixing. Static exposures have limitations such as loss of test material with consequent decrease in

have limitations such as loss of test material with consequent decrease in concentration. Also, the volume of the inhalation chamber poses limitations because of oxygen depletion and carbon dioxide and heat build-up. Nonetheless, the information generated does provide information relevant to potential human exposure patterns. The test material described as "good grade commercial" product does not adequately described the purity of the material produced today.

26.12.2002 (2)

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type	:	Sub-chronic
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	14 days
Frequency of treatm.	:	6 hrs/day for 10 days of exposure over 14 days
Post exposure period	:	
Doses	:	0, 250, 500, 1000, 2000 or 4000 ppm
Control group	:	yes
Method	:	other: Consistent with OECD 412, and US EPA guidelines.
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane

Method :

SPECIES/SEX: Male/female Fischer 344/N albino rats

AGE At START OF TEST: 7-8 weeks

ROUTE: Inhalation

DURATION OF TEST: 14 days

DOSE LEVEL(S) and NUMBER OF DOSES: 6 dose levels: 0, 250, 500, 1000, 2000 or 4000 ppm given 6 hrs/day for 10 days of exposure over 14 days. [Doses equivalent to: 0, 1.1, 2.23, 4.46, 8.92, or 17.8 mg/l]

NUMBER OF ANIMALS/DOSE: 5M/5F per dose, housed 1/sex/cage

VEHICLE: None

STUDY METHOD: Groups of 5 male and 5 female Fischer 344/N rats were exposed to air containing bromoethane at targeted concentrations ranging from 250-4000 ppm. There were 10 exposures over a 14 day period lasting 6 hrs/day. Animals were continuously observed during exposure and 2-3 times a day during non-exposure. They were weighed before exposure, at 1 week and at necropsy. Necropsy performed on all animals. Histolopathologic examinations were performed on 3 animals at 1000 and 4000 ppm. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Temperature in the chamber was 71-76 degrees F and humidity was 46-76%. There were 20 air exchanges/hour during non-exposure and 10 exchanges/hour during exposure.

BODY WEIGHT MEASUREMENTS: Prior to first dose, at 1 week and at termination.

FOOD CONSUMPTION/FOOD EFFICIENCY: Food and water available ad libitum.

HEMATOLOGY: Not measured.

CLINICAL CHEMISTRY: None conducted

URINALYSIS: None conducted

ORGAN WEIGHTS: Not performed.

GROSS PATHOLOGY: Complete gross necropsy performed on all animals. List of tissues not provided.

HISTOPATHOLOGY: Histologic examination performed on nasal cavity, trachea, lungs and mainstem bronchi.

CLINICAL OBSERVATIONS: All rats exposed to 2000 and 4000 ppm died before the end of the study. Rats exposed to 2000 ppm were prostrate, dyspneic, lacrimating and twitching b etween days 7 and 10. Hemorrhage and/or acute inflammation of the nasal turbinates, trachea and lungs were seen in 1 rat at 1000 and 1 rat at 2000 ppm. The final mean body weights of rats (both sexes) exposed to 250, 500, or 1000 ppm were comparable to the controls.

Remark : REASON: There were no data on food consumption or organ weights and the necropsy findings were not reported (they were summarized). Further, the limited histopathological examinations performed did not indicate what sex was examined per dose group.

Result : FINDINGS/MEASURED ENDPOINT/INDEX (i.e. LOEL, NOEL): Based upon the clinical observations at 1000, 2000 and 4000 ppm, and mortality at 2000 and 4000 ppm, the NOAEL was 500 ppm.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Reliability : (2) valid with restrictions
DATA QUALITY: Study was conducted in accordance with recognized scientific protocols for a 2-week range finding study. The data support the conclusions and recommendations for dose selection in longer term inhalation studies, which was the purpose of the stud y. Test material was fully characterized and analyzed.

fully characterized and analyzed.

26.12.2002 (6) (6)

Type	:	Sub-chronic
Species	:	rat
Sex	:	male/female
Strain	:	Fischer 344
Route of admin.	:	inhalation
Exposure period	:	6 hrs/day, 5 days/week for 14 weeks of exposure
Frequency of treatm.	:	14 weeks
Post exposure period	:	
Doses	:	0, 100, 200, 400, 800 or 1600 ppm
Control group	:	yes
Method	:	other: Consistent with OECD 413, and US EPA guidelines.
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane

Method :

SPECIES/SEX: Male/female Fischer 344/N albino rats

AGE at Start of Test: 7-8 weeks

ROUTE: Inhalation

DURATION OF TEST: 14 weeks.

DOSE LEVEL(S) and NUMBER OF DOSES: 6 dose levels: 0, 100, 200, 400, 800 or 1600 ppm given 6 hrs/day, 5 days/week for 14 weeks of exposure. [Doses equivalent to: 0, 0.45, 0.89, 1.78, 3.57, or 7.13 mg/l].

NUMBER OF ANIMALS/DOSE: 10M/10F per dose, housed 1/sex/cage

VEHICLE: None

STUDY METHOD: Groups of 10 male and 10 female Fischer 344/N rats were exposed to air containing bromoethane at targeted concentrations ranging from 100-1600 ppm. There were 65 exposures over a 14 week period lasting 6 hrs/day. Animals were observed continuously during exposure and 3 times a day during non-exposure periods. They were weighed before exposure and once a week thereafter. Necropsy performed on all animals. Histologic examination performed on control and 800 and 1600 ppm animals. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Temperature in the chamber was 72-77 degrees F and humidity was 37-80%. There were 10 exchanges/hour.

BODY WEIGHT MEASUREMENTS: Prior to first dose, once a week and at termination.

FOOD CONSUMPTION/FOOD EFFICIENCY: Not stated. Food available ad libitum during non-exposure. Water available at all times.

HEMATOLOGY: Not measured.

CLINICAL CHEMISTRY: None conducted

URINALYSIS: None conducted

ORGAN WEIGHTS: Livers were weighed at necropsy.

GROSS PATHOLOGY: Complete gross necropsy performed on all animals. List of tissues examined included: adrenal glands, brain, colon, duodenum, epididymis, esophagus, harderian gland, heart, ileum, jejunum, kidneys, larynx, liver, lungs and bronchi, mammary gland, mandibular lymph nodes, nasal cavity and turbinates, ovaries, pancreas, parathyroid glands, pituitary gland, preputial or clitoral gland, prostate, rectum, salivary glands, skin, spleen, sternebrae plus marrow, stomach, testes, thymus, uterus, thyroid gland, trachea, tracheobronchial lymph nodes and urinary bladder.

HISTOPATHOLOGY: Histologic examination performed on control, 800 and 1600 ppm dose groups in tissues listed above.

CLINICAL OBSERVATIONS: There were 4/10 males and 2/10 females that died during the study at 1600 ppm. The final mean body weights of male and female rats exposed to 1600 ppm were lower than controls (43-58%). At 1600 ppm, rats displayed ataxia, posterior paresis, dyspnea and dacryorrhea.

Remark : REASON: The study did not provide detailed cageside information regarding symptoms, clinical chemistry and hematology data or organ weight information. Detailed information was also not provided for the gross necropsy and histopathological examinations.

Result : FINDINGS/MEASURED ENDPOINT/INDEX (i.e. LOEL, NOEL): Mean liver to body weight ratios in females were significantly increased at 800 and 1600 ppm, and increased in males at 1600 ppm. Compound-related lesions were observed at 1600 ppm but not at lower dose levels. Based upon these findings an NOAEL of 400 ppm was demonstrated.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Attached document : RD3LesionTable.doc

Reliability : (2) valid with restrictions
DATA QUALITY: Study was conducted in accordance with recognized scientific protocols for a 14-week repeated dose inhalation study, except for the lack of clinical chemistry and hematological measurements. The data support the conclusions and recommendations for dose selection in the longer term 2 year inhalation carcinogenicity study, which was the purpose of the study. The study clearly identifies the toxicity in rats following inhalation to monitored levels of a test material 6 hours/day, 5 days/week for 14 weeks. Test material was fully characterized and analyzed.

26.12.2002 (6)

Type : Chronic
Species : rat
Sex : male/female
Strain : Fischer 344
Route of admin. : inhalation
Exposure period : 104 weeks
Frequency of treatm. : 6 hrs/day, 5 days/week
Post exposure period :
Doses : 0, 100, 200 or 400 ppm
Control group : yes
Method : other: Consistent with OECD 451, and US EPA guidelines.
Year : 1989
GLP : yes
Test substance : other TS: Bromoethane

Method : SPECIES/SEX: Male/female Fischer 344/N albino rats

AGE AT START OF TEST: 8-10 weeks

ROUTE: Inhalation

DURATION OF TEST: 2 years.

DOSE LEVEL(S) and NUMBER OF DOSES: 3 dose levels: 0, 100, 200 or 400 ppm given 6 hrs/day, 5 days/week for 104 weeks of exposure.

NUMBER OF ANIMALS/DOSE: 50M/50F per dose, housed 1/sex/cage

VEHICLE: None

STUDY METHOD: Groups of 50 male and 50 female Fischer 344/N rats were exposed to air containing bromoethane at targeted concentrations 0, 100, 200 or 400 ppm. Exposures lasted 6 hrs/day, 5 days/week for 104 weeks. Animals were observed continuously during exposure and 2 times a day during non-exposure periods. They were weighed before exposure and once a week for 12 weeks, then once per month until termination. A full necropsy was performed on all animals found moribund or dead. Complete histopathologic examination performed on all control and high dose animals, on low dose animals dying during study and on grossly visible lesions. Also, all target organs/tissues from all dose groups were examined at necropsy. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Temperature in the chamber was 67-83 degrees F and humidity was 33-84%. There were 10 exchanges/hour.

BODY WEIGHT MEASUREMENTS: Prior to first dose, once a week for 12 weeks, and monthly thereafter until termination.

FOOD CONSUMPTION/FOOD EFFICIENCY: Not stated. Food available ad libitum during non-exposure. Water available at all times.

HEMATOLOGY: Not measured.

CLINICAL CHEMISTRY: None conducted

URINALYSIS: None conducted

ORGAN WEIGHTS: Not performed.

GROSS PATHOLOGY: Complete gross necropsy and histologic examinations performed on all animals. List of tissues examined included: adrenal glands, brain, colon, duodenum, epididymis/prostate/testes, esophagus, gross lesions and tissue masses with regional lymph nodes, heart, ileum, jejunum, kidneys, larynx, liver, lungs and bronchi, mammary gland, mandibular lymph nodes, nasal cavity and turbinates, ovaries/uterus, pancreas, parathyroid glands, pituitary gland, preputial gland or clitoral gland, rectum, salivary glands, skin, spleen, sternebrae including marrow, stomach, thymus, thyroid gland, trachea, tracheobronchial lymph nodes and urinary bladder.

HISTOPATHOLOGY: Histologic examination performed on all animals in tissues listed above. Tissues too autolyzed or cannibalized were not subjected to histologic exam.

STATISTICAL ANALYSIS: Probability of survival was estimated by the

STATISTICAL ANALYSIS: Probability of survival was estimated by the product-limit procedure of Kaplan and Meier (1958). Possible dose-related effect on survival using the method of Cox (1972) for groups and Tarone's (1975) life table for dose-related trends. All reported P values for survival were two-sided. Tumor analyses were examined using life table test (Cox, 1972; Tarone, 1975) and Fisher's exact test and Cochran-Armitage trend test (Armitage, 1971; Gart, 1979). Test of significance included pairwise comparisons of each dose group with controls and a test for overall dose response trend.

CLINICAL OBSERVATIONS: There was no compound related effect on mortality and survival in all dose groups were comparable to controls. Animals surviving until study termination are as follows: Male: 17, 26, 27 and 21 in the 0, 100, 200 and 400 ppm groups; Female: 19, 29, 24 and 23 in the 0, 100, 200 and 400 ppm groups. The final mean body weight of male and female rats exposed to bromoethane were comparable to controls. There were no compound related clinical signs observed or reported except for increased conjunctivitis in 400 ppm females.

Result : FINDINGS/MEASURED ENDPOINT/INDEX (i.e. LOEL, NOEL): The main purpose of the bioassay was to assess the carcinogenic potential rather than establish a NOAEL. There was "equivocal evidence" of carcinogenic activity for female Fischer 344/N rats, based upon the presence of brain gliomas and alveolar/bronchiolar adenomas. There was "some" evidence of carcinogenic activity for male rats based upon pheochromocytomas in the adrenal, granular cell tumors and glial cell tumors in the brain, and alveolar/bronchiolar adenomas and carcinomas in the lung. The incidence of each of these tumors was not related to dose, and there were no statistically significant differences from controls.

Two malignant pheochromocytomas in the 200 ppm males metastasized to the lung and lymph nodes. The majority of the pheochromocytomas were microscopic and not diagnosed grossly. The incidence of glial cell tumors in dose groups was not significantly greater than historical control data from this lab. Also, the incidence of alveolar/bronchiolar adenomas or carcinomas in dose groups was not significantly greater than the historical control data from the same lab. Suppurative inflammation of the nasal cavity, larynx, lungs and salivary glands was increased in dosed rats compared to controls.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Attached document : C A1LesionTables.doc

Reliability : (1) valid without restriction
DATA QUALITY: Study was conducted in accordance with recognized scientific protocols for a 2 year carcinogenicity study conducted via the inhalation route of exposure. The study was conducted in accordance with GLP standards and clearly identifies the oncogenicity/toxicity to rats following inhalation to monitored levels of a test material 6 hours/day, 5 days/week for 2 years. Test material was fully characterized and analyzed.

26.12.2002 (6)

Type : Sub-acute
Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : inhalation
Exposure period : 14 days
Frequency of treatm. : 6 hrs/day for 10 days of exposure over 14 days

Post exposure period	:	
Doses	:	0, 250, 500, 1000, 2000 or 4000 ppm
Control group	:	yes
Method	:	other: Consistent with OECD 412, and US EPA guidelines.
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane

Method : SPECIES/SEX: Male/female B6C3F1 mice.

AGE at Start of Test: 8-9 weeks

ROUTE: Inhalation

DURATION OF TEST: 14 days

DOSE LEVEL(S) and NUMBER OF DOSES: 6 dose levels: 0, 250, 500, 1000, 2000 or 4000 ppm given 6 hrs/day for 10 days of exposure over 14 days. [Doses equivalent to: 0, 1.1, 2.23, 4.46, 8.92, or 17.8 mg/l]

NUMBER OF ANIMALS/DOSE: 5M/5F per dose, housed 1/sex/cage

VEHICLE: None

STUDY METHOD: Groups of 5 male and 5 female B6C3F1 mice were exposed to air containing bromoethane at targeted concentrations ranging from 250-4000 ppm. There were 10 exposures over a 14 day period lasting 6 hrs/day. Animals were continuously observed during exposure and 2-3 times a day during non-exposure. They were weighed before exposure, at 1 week and at necropsy. Necropsy performed on all animals. Histolopathologic examinations were performed on 3 animals at 1000 and 4000 ppm. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Temperature in the chamber was 71-76 degrees F and humidity was 46-76%. There were 20 air exchanges/hour during non-exposure and 10 exchanges/hour during exposure.

BODY WEIGHT MEASUREMENTS: Prior to first dose, at 1 week and at termination.

FOOD CONSUMPTION/FOOD EFFICIENCY: Food and water available ad libitum.

HEMATOLOGY: Not measured.

CLINICAL CHEMISTRY: None conducted

URINALYSIS: None conducted

ORGAN WEIGHTS: Not performed.

GROSS PATHOLOGY: Complete gross necropsy performed on all animals. List of tissues not provided.

HISTOPATHOLOGY: Histologic examination performed on nasal cavity, trachea, lungs and mainstem bronchi.

CLINICAL OBSERVATIONS: All mice exposed to 2000 and 4000 ppm died before the end of the study. Mice exposed to 2000 ppm were prostrate and dyspneic. Minimal pulmonary congestion and mild pulmonary hemorrhage

dyspneic. Minimal pulmonary congestion and mild pulmonary hemorrhage was seen at 1000 ppm, The final mean body weights of mice (both sexes) exposed to 250, 500, or 1000 ppm were comparable to the controls.

Remark : REASON: There were no data on food consumption or organ weights and the necropsy findings were not reported (they were summarized). Further, the limited histopathological examinations performed did not indicate what sex was examined per dose group.

Result : FINDINGS/MEASURED ENDPOINT/INDEX (i.e. LOEL, NOEL): Based upon the clinical observations at 1000, 2000 and 4000 ppm , and mortality at 2000 and 4000 ppm, the NOAEL was 500 ppm.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Reliability : (2) valid with restrictions
DATA QUALITY: Study was conducted in accordance with recognized scientific protocols for a 2-week range finding study. The data support the conclusions and recommendations for dose selection in longer term inhalation studies, which was the purpose of the study. Test material was fully characterized and analyzed.

26.12.2002 (6)

Type : Sub-chronic
Species : mouse
Sex : male/female
Strain : B6C3F1
Route of admin. : inhalation
Exposure period : 6 hrs/day, 5 days/week for 14 weeks of exposure
Frequency of treatm. : 14 weeks
Post exposure period :
Doses : 0, 100, 200, 400, 800 or 1600 ppm
Control group : yes
Method : other: Consistent with OECD 413, and US EPA guidelines.
Year : 1989
GLP : yes
Test substance : other TS: Bromoethane

Method : SPECIES/SEX: Male/female B6C3F1 mice.

AGE at Start of Test: 10-12 weeks

ROUTE: Inhalation

DURATION OF TEST: 14 weeks.

DOSE LEVEL(S) and NUMBER OF DOSES: 6 dose levels: 0, 100, 200, 400, 800 or 1600 ppm given 6 hrs/day, 5 days/week for 14 weeks of exposure. [Doses equivalent to: 0, 0.45, 0.89, 1.78, 3.57, or 7.13 mg/l].

NUMBER OF ANIMALS/DOSE: 10M/10F per dose, housed 1/sex/cage

VEHICLE:None

STUDY METHOD: Groups of 10 male and 10 female B6C3F1 mice were exposed to air containing bromoethane at targeted concentrations ranging from 100-1600 ppm. There were 65 exposures over a 14 week period lasting 6 hrs/day. Animals were observed continuously during exposure and 3 times a day during non-exposure periods. They were weighed before exposure and once a week thereafter. Necropsy performed on all animals. Histologic examination performed on control and 800 and 1600 ppm

Histologic examination performed on control and 800 and 1600 ppm animals. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Temperature in the chamber was 72-77 degrees F and humidity was 37-80%. There were 10 exchanges/hour.

BODY WEIGHT MEASUREMENTS: Prior to first dose, once a week and at termination.

FOOD CONSUMPTION/FOOD EFFICIENCY: Not stated. Food available ad libitum during non-exposure. Water available at all times.

HEMATOLOGY: Not measured.

CLINICAL CHEMISTRY: None conducted

URINALYSIS: None conducted

ORGAN WEIGHTS: Livers were weighed at necropsy.

GROSS PATHOLOGY: Complete gross necropsy performed on all animals. List of tissues examined included: adrenal glands, brain, colon, duodenum, epididymis, esophagus, gallbladder, heart, ileum, jejunum, kidneys, larynx, liver, lungs and bronchi, mammary gland, mandibular lymph nodes, nasal cavity and turbinates, ovaries, pancreas, parathyroid glands, pituitary gland, preputial or clitoral gland, prostate, rectum, salivary glands, skin, spleen, sternebrae plus marrow, stomach, testes, thymus, uterus, thyroid gland, trachea and urinary bladder.

HISTOPATHOLOGY: Histologic examination performed on control, 800 and 1600 ppm dose groups in tissues listed above.

CLINICAL OBSERVATIONS: There were 6/10 males and 3/10 females that died during the study. Mortality occurred as follows: Males: 400 ppm - 1/10, 800 ppm - 2/10 (1 accidental), and 1600 ppm - 3/10; Females: 200 ppm - 1/10 (accidental), 400 ppm - 1/10 (accidental), 800 ppm - 0/10, and 1600 ppm - 1/10. The final mean body weights of male and female mice exposed to 1600 ppm were @15%lower than controls. At 1600 ppm, mice displayed clinical signs of ataxia and tremors.

Remark : REASON: The study did not provide detailed cageside information regarding symptoms, clinical chemistry and hematology data or organ weight information. Detailed information was also not provided for the gross necropsy and histopathological examinations.

Result : FINDINGS/MEASURED ENDPOINT/INDEX (i.e. LOEL, NOEL): Mean liver to body weight ratios were not effected. Positive titers were seen for Sendai virus in 10/10 mice at the end of the study in the 1600 ppm group.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Attached document : RD4LesionTable.doc

Reliability : (2) valid with restrictions
DATA QUALITY: Study was conducted in accordance with recognized scientific protocols for a 14-week repeated dose inhalation study, except for the lack of clinical chemistry and hematological measurements. The data support the conclusions and recommendations for dose selection in the longer term 2 year inhalation carcinogenicity study, which was the purpose

longer term 2 year inhalation carcinogenicity study, which was the purpose of the study. The study clearly identifies the toxicity in mice following inhalation to monitored levels of a test material 6 hours/day, 5 days/week for 14 weeks. Test material was fully characterized and analyzed.

26.12.2002 (6)

Type	:	Chronic
Species	:	mouse
Sex	:	male/female
Strain	:	B6C3F1
Route of admin.	:	inhalation
Exposure period	:	104 weeks
Frequency of treatm.	:	6 hrs/day, 5 days/week
Post exposure period	:	
Doses	:	0, 100, 200 or 400 ppm
Control group	:	yes
Method	:	other: Consistent with OECD 451, and US EPA guidelines.
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane

Method :

SPECIES/SEX: Male/female B6C3F1 mice.

AGE AT START OF TEST: 9 weeks

ROUTE: Inhalation

DURATION OF TEST: 2 years.

DOSE LE VEL(S) and NUMBER OF DOSES: 3 dose levels: 0, 100, 200 or 400 ppm given 6 hrs/day, 5 days/week for 103 weeks of exposure.

NUMBER OF ANIMALS/DOSE: 50M/50F per dose, housed 1/sex/cage

VEHICLE: None

STUDY METHOD: Groups of 50 male and 50 female B6C3F1 mice were exposed to air containing bromoethane at targeted concentrations 0, 100, 200 or 400 ppm. Exposures lasted 6 hrs/day, 5 days/week for 104 weeks. Animals were observed continuously during exposure and 2 times a day during non-exposure periods. They wer e weighed before exposure and once a week for 12 weeks, then once per month until termination. A full necropsy was performed on all animals found moribund or dead. Complete histopathologic examination performed on all control and high dose animals, on lowdose animals dying during study and on grossly visible lesions. Also, all target organs/tissues from all dose groups were examined at necropsy. The test material was vaporized without applied heat and introduced into the exposure chamber via the fresh air duct. Material was diluted with air employing a micrometering pump with adjustable rates. Concentrations of bromoethane in the chamber were measured by gas chromatography equipped with a flame ionization detector. Temperature in the chamber was 67-83 degrees F and humidity was 33-84%. There were 10 exchanges/hour.

BODY WEIGHT MEASUREMENTS: Prior to first dose, once a week for 12 weeks and then once a month until termination.

FOOD CONSUMPTION/FOOD EFFICIENCY: Not stated.

HEMATOLOGY: Not measured.

CLINICAL CHEMISTRY: None conducted

URINALYSIS: None conducted

ORGAN WEIGHTS: Not performed.

GROSS PATHOLOGY: Complete gross necropsy performed on all animals. List of tissues examined for all animals included: adrenal glands, brain, colon, duodenum, epididymis/prostate/testes, esophagus, gallbladder, gross lesions and tissue masses with regional lymph nodes, heart, lieum, jejunum, kidneys, larynx, liver, lungs and bronchi, mammary gland, mandibular lymph nodes, nasal cavity and turbinates, ovaries/uterus, pancreas, parathyroid glands, pituitary gland, rectum, salivary glands, skin, spleen, sternebrae including marrow, stomach, thymus, thyroid gland, trachea, tracheobronchial lymph nodes and urinary bladder. Nasal cavity and gross lesions examined for low dose mice.

HISTOPATHOLOGY: Histologic examination performed on all animals in tissues listed above. Also, target tissues and animals dying in lower dose groups were examined.

CLINICAL OBSERVATIONS: Survival of females at 400 ppm was significantly lower th an controls. No other effects on survival in either sex were observed. Animals surviving until study termination are as follows: Male: 35, 37, 30 and 34 in the 0, 100, 200 and 400 ppm groups; Female: 36, 37, 37 and 23 in the 0, 100, 200 and 400 ppm groups. The final mean body weight of male and female rats at 400 ppm was 1-9% and 6-16% lower than controls, respectively. There were no compound related clinical signs observed or reported.

Result : FINDINGS/MEASURED ENDPOINT/INDEX (i.e. LOEL, NOEL): The main purpose of the bioassay was to assess the carcinogenic potential rather than establish a NOAEL. There was "equivocal evidence" of carcinogenic activity for male B6C3F1 mice, based upon the presence of alveolar/bronchiolar adenomas and carcinomas in the l ung. In female mice there was "clear" evidence of carcinogenicity based upon adenomas, adenocarcinomas, and squamous cell carcinomas in the uterus.

Increased non-neoplastic findings included suppurative inflammation in the lungs of 200 and 400 ppm females , and suppurative inflammation in the uterus and ovaries of all dose females.

The incidence of endometrial adenomas, adenocarcinomas, and squamous cell carcinomas were significantly increased in dosed female groups compared to control. The incidence in the 400 ppm female group probably contributed to the increased mortality at this level. There was a positive trend for increase in lung tumors in males, which was significant at 400 ppm compared to controls.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Attached document : C A2LesionTable.doc

Reliability : (1) valid without restriction

DATA QUALITY: Study was conducted in accordance with recognized scientific protocols for a 2 year carcinogenicity study conducted via the inhalation route of exposure. The study was conducted in accordance with GLP standards and clearly identifies the oncogenicity/toxicity to mice following inhalation to monitored levels of a test material 6 hours/day, 5 days/week for 2 years. Test material was fully characterized and analyzed.

5.5 GENETIC TOXICITY 'IN VITRO'

Type	:	Ames test
System of testing	:	Salmonella typhimurium strains: TA98 and TA100
Test concentration	:	6 concentrations (0.01 - 0.15 ug/plate)
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	
Method	:	other: Consistent with OECD Guideline 471, Ames et al. (1975), and Haworth et al. (1983)
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane

Method :

TEST ORGANISM USED: Salmonella typhimurium strains: TA98 and TA100.

TEST COMPOUND CONCENTRATIONS USED: 6 concentrations (0.01 - 0.15 ug/plate) were evaluated in triplicate along with appropriate positive controls for TA100; 5 concentrations (0.01 - 1 ug/plate) were evaluated in triplicate along with appropriate positive controls for TA98.

CONTROL MATERIALS: The following control materials were employed.

Positive Control:
Metabolic Non-activation:
Sodium azide: for TA100 (concentration not reported)
4-nitro-0-phenylenediamine: for TA98 (concentration not reported)

Metabolic Activation (using both Hamster and Rat S9):
2-aminoanthracene: all strains (concentration not reported)

ACTIVATION: Aroclor 1254-induced rat liver from male Sprague-Dawley rats and Syrian hamsters.

TEST PERFORMANCE: A modification of the Ames Standard plate assay. The test chemical was incubated with each Salmonella typhimurium strain with S9 mix (metabolic activation enzymes and cofactors from Aroclor 1254-induced male Sprague-Dawley rat or Syrian hamster liver) or without S9 on glucose agar plates. The plates were inverted without lids on a perforated porcelain plate in glass desiccator jars. The test material was pipetted into a glass dish set below the Petri dishes in each jar and then sealed. The test material was circulated and mixed throughout with magnetic stirrers placed inside the apparatus. This entire apparatus was incubated for 24 hours at 37 degrees C. The plates were removed from this apparatus and incubated for another 24 hours at 37 degrees C. Each test consisted of triplicate plates of concurrent positive and negative controls and each dose concentration.

Remark : Also published in Environmental and Molecular Mutagenesis 19, Supplement 21: 2-141 (1992); authors: E. Zeiger, B.E. Anderson, S. Haworth, T. Lawlor and K. Mortelmans.

Result : REPORT RESULTS : Mutation assay: Test compound induced a significant increase in the number of revertant colonies over that shown in the solvent control plates for strain TA100 with and w/o S9 activation. There was no mutagenic activity with TA98, with or without S9. Positive controls produced the expected response in all experiments.

CONCLUSION: Test material was mutagenic in S. typhimurium TA 100 with and w/o S9 activation.

Test substance	:	TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.
Attached document	:	MU1ResultsTable.doc
Reliability	:	(2) valid with restrictions DATA QUALITY: Study was conducted in accordance with recognized published scientific procedure for examining the mutagenic potential of a test compound in selected S. typhimurium bacteria strains, TA 98 and TA 100. Test method utilized recognized positive controls that gave the expected positive responses, confirming the sensitivity of the method. The study meets minimum scientific standards and supports the conclusion that the test material was positive in this study, with respect to Salmonella typhimurium strain TA 100 only.

27.12.2002 (6)

Type	:	Cytogenetic assay
System of testing	:	Chinese hamster ovary (CHO) cells in culture
Test concentration	:	
Cycotoxic concentr.	:	
Metabolic activation	:	with and without
Result	:	positive
Method	:	other: Conforms to OECD test guideline 479, and US EPA Guidelines.
Year	:	1989
GLP	:	yes
Test substance	:	other TS: Bromoethane

Method :

TEST ORGANISM USED: Chinese hamster ovary (CHO) cells in culture were obtained from Dr. Sheila Galloway (Litton Bionetics) at their 5th passage level after cloning and designated CHO-LB. Cells were free of mycoplasma. Cells were not used beyond their 15th passage after cloning to be assured of karyotypic stability. Cultures were handled under gold lights to prevent photolysis of bromodeoxyuridine (BrdU)-substituted DNA.

TEST COMPOUND CONCENTRATIONS USED: Each test consisted of concurrent solvent and positive controls and at least 3 dose concentrations of test material. High dose was limited by solubility but did not exceed 5 mg/ml. Two separate trials were performed without S9 mix. The highest dose scored was the one that allowed sufficient M2 cells for analysis.

CONTROL MATERIALS: The following control materials were employed.

Negative control: DMSO

Positive Control:

Metabolic Non-activation:
Mitomycin C: 0.0015 and 0.01 ug/ml

Metabolic Activation:
Cyclophosphamide: 0.5 and 2.5 ug/ml

ACTIVATION: S-9 fraction derived from Aroclor induced Sprague-Dawley rat liver and cofactor mix.

PROTOCOL: In the SCE assay without S9, CHO cells were incubated with the test material for 2 hours at 37 degrees C in McCoy's 5A medium supplemented with 10% fetal bovine serum, L-glutamine (2mM), and anitbiotics. BrdU was added and incubation continued for 24 hours. Cells were washed, fresh medium containing BrdU and colcemid were added,

were washed, fresh medium containing BrdU and colcemid were added, and incubated for another 2-3 hours. In the SCE assay with S9, CHO cells were incubated with test material for 2 hours at 37 degrees C in serum free medium and S9. The medium as removed and replaced with medium containing BrdU (no test chemical) and incubation continued for 26 hours, with colcemid present for the last 2-3 hours. Cells were harvested by mitotic shake-off, fixed and stained with Hoechst 33258 and Giemsa. 50 second-division metaphase cells were scored for frequency of SCEs per cell. A 20% increase in the SCEs/chromosome over the solvent control is considered significant

Remark : Also published in Environmental and Molecular Mutagenesis 13:60-94 (1989); authors: K.S. Loveday, M.H. Lugo, M.A. Resnick, B.E. Anderson, and E. Zeiger.

Result : REPORT RESULTS: Bromoethane was considered positive in all trials.

CONCLUSION: Bromoethane was positive in all trials conducted for SCEs, both with and without S9.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Attached document : MU2ResultsTable.doc

Reliability : (1) valid without restriction
DATA QUALITY: Study was conducted in accordance with recognized published scientific procedure for examining the in vitro cytogenetic potential of a test compound in Chinese hamster ovary cells in culture. Test method utilized recognized positive controls that gave the expected positive responses, confirming the sensitivity of the method. The study meets acceptable scientific standards and supports the conclusion that the test material was positive in this study.

18.12.2002 (7)

Type : Chromosomal aberration test
System of testing : Chinese hamster ovary (CHO) cells in culture
Test concentration : 0, 100, 300 and 1000 ug/ml
Cycotoxic concentr. :
Metabolic activation : with and without
Result : negative
Method : other: Conforms to OECD test guideline 473, and US EPA Guidelines.
Year : 1989
GLP : yes
Test substance : other TS: Bromoethane

Method : TEST ORGANISM USED: Chinese hamster ovary (CHO) cells in culture were obtained from Dr. Sheila Galloway (Litton Bionetics) at their 5th passage level after cloning and designated CHO-LB. Cells were free of mycoplasma. Cells were not used beyond their 15th passage after cloning to be assured of karyotypic stability. Cultures were handled under gold lights to prevent photolysis of bromodeoxyuridine (BrdU)-substituted DNA.

TEST COMPOUND CONCENTRATIONS USED: Bromoethane was tested without S9 metabolic activation and with S9 metabolic activation. Concentrations were 0, 100, 300 and 1000 ug/ml. Test concentrations were empirically chosen based upon toxicity and cell cycle delay noted in the SCE experiment. The highest dose analyzed was the one that yielded a sufficient number of suitable metaphase cells, but did not exceed 5mg/ml.

CONTROL MATERIALS: The following control materials were employed.

Negative control: DMSO

Negative control: DMSO

Positive Control:
Metabolic Non-activation:
Mitomycin C: 5 ug/ml

Metabolic Activation:
Cyclophosphamide: 50 ug/ml

ACTIVATION: S-9 fraction derived from Aroclor induced Sprague-Dawley rat liver and cofactor mix.

PROTOCOL: CHO cells without S9 were incubated at 37 degrees C in McCoy's 5A medium with test material for 8-10 hours. Colcemid was added to arrest cells in the first metaphase and incubated for an additional 2-3 hours. Cells were harvested by mitotic shake-off, fixed and stained with 6% Giemsa. CHO cells with S9 and test chemical were incubated at 37 degrees C for 2 hours. Treatment medium was removed and cells incubated at 37 degrees C for 8-10 hours in fresh medium, with colcemid present for the last 2-3 hours. Cells were harvested and fixed as cells without S9.

Remark : Also published in Environmental and Molecular Mutagenesis 13:60-94 (1989); authors: K.S. Loveday, M.H. Lugo, M.A. Resnick, B.E. Anderson, and E. Zeiger.

Result : REPORT RESULTS: Bromoethane was considered negative with and without metabolic activation.

CONCLUSION: Bromoethane was negative for chromosomal aberrations, both with and without S9 activation..

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid; turns yellow when exposed to air; mol. Wt. is 109; sp. Gravity is 1.4505 between 4 and 25 degrees C; boiling point is 38.4 degrees C; melting point is-119 degrees C; vapor pressure is 475 mm mercury at 25 degrees C; solubility in water is 0.91% (w/w) at 20 degrees C; miscible in ethanol, ethyl ether, chloroform and other organic solvents. Purity and identity of each lot analyzed by Midwest Research Institute.

Attached document : MU3ResultsTable.doc

Reliability : (1) valid without restriction
DATA QUALITY: Study was conducted in accordance with recognized published scientific procedure for examining the in vitro cytogenetic potential of a test compound in Chinese hamster ovary cells in culture. Test method utilized recognized positive controls that gave the expected positive responses, confirming the sensitivity of the method. The study meets acceptable scientific standards and supports the conclusion that the test material was positive in this study.

26.12.2002 (7)

Type : Mitotic recombination in Saccharomyces cerevisiae
System of testing : Saccharomyces cerevisiae D3
Test concentration : 0, 0.2, 0.4, 0.6% (2000, 3000 and 4000 ppm)
Cycotoxic concentr. :
Metabolic activation : with and without
Result : positive
Method : other: Prior to OECD test guidelines Conformed to the method of Zimmermann, et al., 1967.
Year : 1976
GLP :
Test substance : other TS: Bromoethane

Method : TEST ORGANISM USED: Yeast Saccharomyces cerevisiae D3 that is diploid heterozygous for a mutation in an adenine-metabolizing enzyme. The test strain is grown overnight at 30 degrees C with aeration in 1% tryptone and and 0.5% yeast extract. The cells are washed twice in 0.067M

tryptone and and 0.5% yeast extract. The cells are washed twice in 0.067M phosphate buffer at pH 7.4 and resuspended in the same buffer at a concentration of 10E8 cells/ml.

TEST COMPOUND CONCENTRATIONS USED: Bromoethane was tested with and without S9 metabolic activation. Concentrations of bromoethane used were 0, 0.2, 0.4, 0.6% (2,000; 3,000, and 4,000 ppm). Test material was introduced to the yeast suspension under a desiccator, then sealed to prevent escape. The air was constantly stirred within the desiccator. Test material had completely evaporated within the first 30 minutes.

CONTROL MATERIALS: The following control materials were employed.

Negative control: DMSO

Positive Control:
Metabolic Non-activation:
1,2,3,4-diepoxybutane

Metabolic Activation:
1,2,3,4-diepoxybutane

ACTIVATION: Adult male mice were given a single i.p. injection of Aroclor 1254 (500 mg/kg) and five days later there livers were removed and the S9 postmitochondrial supernatant prepared.

PROTOCOL: The suspension assay consists of 5 x 10E7 washed, stationary-phase yeast cells in 1 ml of 0.067M phosphate buffer, pH 7.4 and enough test material to produce 50% killing. This suspension is incubated at 30 degrees C for 4 hours, then diluted serially in sterile saline. This is then plated on tryptone-yeast agar plates. Plates of a 10E-3 dilution are incubated for 2 days at 30 degrees C, then 2 d ays at 4 degrees C to enhance development of the red pigment (indicating adenine-negative homozygosity). Plates are scanned with a dissecting microscope. Plates at 10E-5 dilution are incubated for 2 days at 30 degrees C to determine the total number of colony forming units. For activation, the S9 fraction is added to the incubation mixture.

Result : REPORT RESULTS: Bromoethane was considered positive with and without metabolic activation.

CONCLUSION: Bromoethane increased the mitotic recombination frequency 3 to 5-fold and is a weak mutagen to yeast cells.

Test substance : TEST MATERIAL: Bromoethane; purity >98%; clear colorless, volatile, flammable liquid.

Attached document : MU4ResultsTable.doc

Reliability : (2) valid with restrictions
DATA QUALITY: Study was conducted in accordance with recognized published scientific procedure for examining in vitro mitotic recombination in yeast cells. Test method utilized a positive control that gave the expected positive response, confirming the sensitivity of the method. The study meets acceptable scientific standards and supports the conclusion that the test material was positive in this study.

26.12.2002 (5)

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

(1) Aerospace Medical Research Laboratory, Aerospace Medical Division, Air Force Systems Command Wright-Patterson AFB, Ohio; Contract No. F33615-76-C-5005. Acute Toxicity and Skin Corrosion Data for Some Organic and Inorganic Compounds and Aqueous Solutions; Toxicology and Applied Pharmacology 42, 417-423 (1977). TESTING FACILITY: University of California, Irvine, Toxic Hazards Research Unit, Overlook Branch, Dayton, Ohio. STUDY NUMBER: AMRL-TR-77-9. STUDY DATE: February 1977. AUTHOR(S): E.H. Vernot, J.D. MacEwen, C.C. Haun, and E.R. Kinkead.

(2) DOW Chemical Company, The National Research Council, and the Bureau of Mines. Physiological Response Attending Exposure to Vapors of Methyl Bromide, Methyl Chloride, Ethyl Bromide and Ethyl Chloride. TESTING FACILITY: Pittsburgh Experimental Station of the Bureau of Mines. STUDY NUMBER(S): Published Report: USTD/PHS, U.S. Public Health Bulletin 185:1-56, US Government Printing Office, Washington, D.C. (1929). STUDY DATE: March 1929. AUTHOR(S): R.R. Sayers, W.P. Yant, B.G.H. Thomas, and L.B. Berger.

(3) Howard and Meylan. Handbook of Physical Properties of Organic Chemicals. CRC PRess, 1997.

(4) Lewis, Sr., R.J.: Sax's Dangerous Properties of Industrial Materials, 9th ed. Van Nostrand Reinhold, New York (1996).

(5) NIOSH and OSHA. In Vitro Microbiological Mutagenicity Studies of Dow Chemical Company Compounds. TESTING FACILITY: SRI International. STUDY NUMBER(S): SRI Project No. LSC-4378; DOW D0006060. STUDY DATE: August 6, 1976. AUTHOR(S): Vincent F. Simmon, Ph.D. and Dennis Poole.

(6) NIOSH and OSHA. Toxicology and Carcinogenesis Studies of Bromoethane (CAS N0. 74-96-4) in Fischer 344/N Rats and B6C3F1 Mice (Inhalation Studies). TESTING FACILITY: Battelle Pacific Northwest Laboratories, Richland, WA; The National Toxicology Program, NIH. STUDY NUMBER(S): NTP Technical Report Series No. 363; NIH Publication No. 90-2818. STUDY DATE: January 1989. AUTHOR: Joseph Roycroft, Ph.D., Study Scientist.

(7) NIOSH and OSHA. Toxicology and Carcinogenesis Studies of Bromoethane (CAS N0. 74-96-4) in Fischer 344/N Rats and B6C3F1 Mice (Inhalation Studies). TESTING FACILITY: SRI International. STUDY NUMBER(S): NTP Technical Report Series No. 363; NIH Publication No. 90-2818. STUDY DATE: January 1989. AUTHOR: Joseph Roycroft, Ph.D., Study Scientist.

(8) Patty's Industrial Hygiene and Toxicology, 4th ed. Toxicology, Vol 2E, Clayton, G.D.; Clayton, F.E.., Eds New York: John Wiley & Sons, Inc., pp 4087-4091 (1994).

(9) Sittig, M. (1979) Methyl (and ethyl) bromide. Hazardous and Toxic Effects of Industrial Chemicals. Park Ridge, NJ: Noyes Data Corp., pp 298-299.

(10) The International Technical Information Institute (ITII) (1979). Toxic and Hazardous Industrial Chemicals Safety Manual for Handling and Disposal with Toxicity and Hazard Data. Tokyo: ITII, pp. 221-222.

(11) The Merck Index (Merck) (1983) 10th ed. Rahway, NJ: Merck & Co., Inc., p 547.

I U C L I D

Data Set

Existing Chemical	:	ID: 74-83-9
CAS No.	:	74-83-9
EINECS Name	:	bromomethane
EC No.	:	200-813-2
TSCA Name	:	Methane, bromo-
Molecular Formula	:	CH3Br

Producer related part

Company	:	GREAT LAKES CHEMICAL CORPORATION
Creation date	:	18.12.2002

Substance related part

Company	:	GREAT LAKES CHEMICAL CORPORATION
Creation date	:	18.12.2002
Status	:	
Memo	:	
Printing date	:	26.12.2002
Revision date	:	
Date of last update	:	26.12.2002
Number of pages	:	11
Chapter (profile)	:	Chapter: 3, 4
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

3.1.1 PHOTODEGRADATION

DIRECT PHOTOLYSIS

Halflife t1/2	:	= 208.8 - 305.4 hour(s)
Degradation	:	% after
Quantum yield	:	
Deg. product	:	
Method	:	other (measured): US EPA Pesticide Assessment Guidelines, Subdivision N; OECD guideline OECD 111.
Year	:	1993
GLP	:	yes
Test substance	:	other TS: Methyl Bromide
Method	:	STUDY OBJECTIVES: Determine whether photohydrolysis in aqueous conditions is a significant degradation pathway for methyl bromide; identify photoproducts >10%; estimate the half-life for methyl bromide stored in the dark and exposed to artificial sunlight. OTHER MATERIALS: Methanol 99.8%; ethyl acetate 99.97%, methane 99% and nanograde water Type II or Grade II deionized, charcoal filtered and sterilized. CONCENTRATIONS OF TEST SUBSTANCES: Test solution was 108 ppm methyl bromide in separate buffers of pH 5, 7, and 9. The methyl bromide standard was 2 to 100 ppm in a pH7 buffer. The methanol standard was 2 to 35 ppm in a pH 7 buffer. EXPOSURE PERIOD: Degradation was followed over a time course of 572 hours. TEST PROCEDURE: The degradation of methyl bromide solutions was observed over time and compared to identical solutions stored in the dark at 25 degrees C. Eight sampling intervals were incorporated and included analyses of methyl bromide, methanol, methane, inorganic bromide and pH. Temperature in the incubator and photoexposed vials was maintained at 25 degrees C. In order to control the experiment for the volatility of methyl bromide, the 2 cc autosampler vials were pressure-sealed with no headspace (to prevent evaporation). The vials were also inverted in the circulating water bath to reduce volatility losses. Total vial length was 2.5 cm and about 2 cm was exposed to the light source (Heraeus SUNTEST CPS), a simulated outdoor sunlight. Test vials maintained in the dark were wrapped in aluminum foil to prevent photolysis. All test solutions were analyzed in triplicate for the first two sampling intervals, and then in quintuplicate thereafter. The molar concentration of each component at each interval was quantitated for each sample and a material balance for each analytical point was determined. Each analysis was performed using a GC with a flame ionization detector.
Result	:	RESULTS: A first order rate of kinetics for photohydrolysis was determined. The half-lives at each pH was determined from the 8 time-point measurements: t ½ at pH 5 = 212 hrs; at pH 7 = 208.8 hrs; and at pH 9 = 305.4 hrs.
Test substance	:	TEST SUBSTANCE: Methyl bromide, purity 99.8%.
Reliability	:	(1) valid without restriction DATA QUALITY: The study is scientifically sound and valid. The results delineate the processes involved in the photolysis of methyl bromide and the relative rates of this process.

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3.1.2 STABILITY IN WATER

Type	:	abiotic
t1/2 pH4	:	at °C
t1/2 pH7	:	= 255.8 hour(s) at °C
t1/2 pH9	:	= 361 hour(s) at °C
t1/2 pH 5	:	= 258.6 hour(s) at °C
Deg. product	:	
Method	:	other: US EPA Pesticide Assessment Guidelines, Subdivision N; OECD guideline OECD 111.
Year	:	1993
GLP	:	yes
Test substance	:	other TS: Methyl Bromide

Method :

STUDY OBJECTIVES: Determine whether hydrolysis in aqueous conditions is a significant degradation pathway for methyl bromide; identify degradation products >10%; estimate the half-life for methyl bromide stored in the dark.

OTHER MATERIALS: Methanol 99.8%; ethyl acetate 99.97%, methane 99% and nanograde water Type II or Grade II deionized, charcoal filtered and sterilized.

CONCENTRATIONS OF TEST SUBSTANCES: Test solution was 108 ppm methyl bromide(0.001 M) in separate buffers of pH 5, 7, and 9. The methyl bromide standard was 2 to 100 ppm in a pH7 buffer. The methanol standard was 2 to 35 ppm in a pH 7 buffer.

EXPOSURE PERIOD: Degradation was followed over a time course of 570 hours.

TEST PROCEDURE: The degradation of methyl bromide solutions was observed over time for solutions stored in the dark at 25 degrees C. Eight sampling intervals were incorporated and included analyses of methyl bromide, methanol, methane, inorganic bromide and pH. Temperature in the incubator was maintained at 25 degrees C. In order to control the experiment for the volatility of methyl bromide, the 2 cc autosampler vials were pressure-sealed with no headspace (to prevent evaporation. The vials were also inverted in the circulating water bath to reduce volatility losses. Test vials maintained in the dark were wrapped in aluminum foil to prevent photolysis. All test solutions were analyzed in triplicate for the first two sampling intervals, and then in quintuplicate thereafter. The molar concentration of each component at each interval was quantitated for each sample and a material balance for each analytical point was determined. Each analysis was performed using a GC with a flame ionization detector.

Result : RESULTS: A first order rate of kinetics for hydrolysis was determined. The half-lives at each pH was determined from the 8 time-point measurements: t ½ at pH 5 = 258.6 hrs; at pH 7 = 255.8 hrs; and at pH 9 = 361 hrs. The concentration of methane was < 0.1% and not included in the measurements.

Test substance : TEST SUBSTANCE: Methyl bromide, purity 99.8%.

Reliability : (1) valid without restriction
DATA QUALITY: Study follows recognized scientific protocols for hydrolysis studies. The composition of the buffers was provided. The study is scientifically sound and valid. The results delineate the processes involved in the hydrolysis of methyl bromide and the relative rates of this process.

26.12.2002 (1)

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Deg. product	:	
Method	:	other: EPA FIFRA Pesticide Assessment Guidelines, Subpart N, 162-1 and 162-2; OECD Guideline 307, Aerobic and Anaerobic Transformation in Soil
Year	:	1988
GLP	:	yes
Test substance	:	other TS: Methyl Bromide

Method :

STUDY OBJECTIVES: Examine the contribution of chemical reactions and microbial degradation on the environmental fate of methyl bromide.

OTHER MATERIALS:

Soils: Two different soils were tested: a sandy loam (Kimberlina) and a clay loam soil (Panoche clay), collected from an area @100 miles west of Bakersfield, California. This property had been used for crops such as cotton. Soils were screened to remove lumps greater than 0.5 inches. Soil properties were determined and summarized: percent organic matter 0.34% (clay loam) and 0.26% (sandy loam); pH 7 (clay) and 7.3 (sandy); bulk density 0.96 g/cu cm (clay) and 1.44 g/cu cm (sandy). These soils were tested under both aerobic and anaerobic conditions. A total of 4 tests were conducted as follows:

1.Sandy loam - aerobic - 3 sterilized boxes - 3 non-sterilized boxes - 1 control
2.Clay loam - aerobic - 3 sterilized boxes- 3 non-sterilized boxes - 1 control
3.Sandy loam - anaerobic - 3 sterilized boxes - 3 non-sterilized boxes - 1 control
4.Clay loam - anaerobic - 3 sterilized boxes- 3 non-sterilized boxes - 1 control

The soils were both non-sterilized (as received) and sterilized. The soil was sterilized by placing it in an autoclave at 121 degrees C and 15 psi for 2 hours. The difference between the two soil types was used as a measure of the contribution of organics and microbes on the degradation rate. Anaerobic conditions were simulated by replacing oxygen with nitrogen, under the same test conditions. Oxygen content under these conditions was maintained at < 0.5 percent.

was maintained at < 0.5 percent.

CONCENTRATION OF TEST SUBSTANCES: Methyl bromide was added to the soil in boxes at a concentration equivalent to 870 pounds per acre, which was the maximum field dosage rate when applied as a soil fumigant. This was equivalent to 1.25 liters of gas per 1 cubic foot of soil. The initial concentration in the box was 200,000 ppm by volume (theroretical). Concentrations in sandy loam soil ranged from 150,000 to 300,000 (in some cases), depending upon how quickly it was determined. Concentrations in clay loam soil ranged from 160,000 to 200,000.

TEST PROCEDURE: Prior to testing, the half-life in water and soil were determined. The rate of hydrolysis in water was 35 days, and the rate of volatilization from soil was 2 days. Because of this rapid volatilization airtight boxes were designed to retain the methyl bromide. Boxes were stainless steel and consisted of an inner box (containing the soil and methyl bromide) and an outer box to measure any leakage. Methyl bromide was added using a syringe, and an equivalent amount of air was removed during the transfer. The oxygen level was measured and adjusted as necessary (aerobic only). For the anaerobic study, air was replaced with nitrogen. The oygen content was monitored and maintained at < 0.5 percent. Temperature of the boxes was maintained at 23 +/- 3 degrees C. The moisture content of the soil was adjusted to 75% of 0.33 bar moisture. Levels of bromide ion in the soils were determined before the study and at the completion of the study. Also, a portion of the soil was removed to measure for adsorbed methyl bromide.

Methyl bromide losses from the non-sterile soil samples was a measure of both chemical and microbial action and a reaction rate was determined. Methyl bromide loss from sterile soil was a measure of the chemical action only. The difference was a measure of the microbial action.

Samples taken were removed using 10 ml gas-tight syringes through a septum-sealed stainless steel Swagelok fitting. Samples were assayed for methyl bromide, oxygen and carbon dioxide. Samples were collected every 7-10 minutes during the first hour. One to two samples the second hour and a single sample collected at 2 to 3 hour intervals the remainder of the first day. After the first day, sampling frequency was 3 times per day for 2 days, then 1 sample every 2-3 days for the remainder of the study.

Methyl bromide was measured using a GC equipped with a flame ionization detector (FID) and a gas sampling valve. Methyl bromide was confirmed each week using a halogen specific Hall Electrolytic Conductivity Detector (HECD). The oxygen and carbon dioxide levels were measured using a GC equipped with a thermal conductivity detector. Since possible reaction products of methyl bromide with organic compounds or microbial degradation are hydrogen bromide and bromide ion, analyses of these were also performed. Plate count method was used to quantify bacteria and fungi present in the soils. These plates were made up in triplicate to measure CFUs.

Result : RESULTS: The half-life in sandy loam soil, under aerobic conditions, was 35 hours (non-sterilized) and 47 hours (sterilized). Two half-lives were achieved in 20 days and 18 day, respectively. The half-life in sandy loam soil, under anaerobic conditions, was 144 hours (non-sterilized) and 80 hours (sterilized). Two half-lives were achieved in 24 days and 21 days, respectively.
The half-life in clay loam soil, under aerobic conditions, was 3.8 hours (non-sterilized) and 2.5 hours (sterilized). Two half-lives were achieved in 19 days and 11 day, respectively. The half-life in clay loam soil, under anaerobic conditions, was 39 hours (non-sterilized) and 34 hours (sterilized). Two half-lives were achieved in 20 days and 18 days, respectively.

Methyl bromide reduced the level of microbial activity in both soil types. The higher degradation rate for sterile soil was attributed to an adsorption phenomena where more adsorption sites are available on sterile soils because it was off-gassed during sterilization. Once, those sites were saturated the rates of methyl bromide decline for sterile versus non-sterile were the same.

Methyl bromide was rapidly degraded within the first 2-4 hours due to chemical reaction with components in the soil. After 1-2 days a more gradual degradation was observed and is attributed to hydrolysis by moisture in the soil.

Test substance : TEST SUBSTANCE: Methyl bromide, purity 99.8%.

Reliability : (2) valid with restrictions
DATA QUALITY: The study was carried out according to EPA standards and OECD accepted scientific principles. Adequate information is documented that provides confidence in the results and support the conclusions regarding biodegradation under aerobic and anaerobic conditions.

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3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	semistatic
Species	:	Oncorhynchus mykiss (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Limit test	:	
Analytical monitoring	:	yes
Method	:	other: The test was carried out in accordance with FIFRA Subdivision E, Series 72-1, and is comparable to OECD Test Guideline 203.
Year	:	1993
GLP	:	yes
Test substance	:	other TS: Methyl Bromide

Method :

SPECIES: Rainbow Trout (Oncorhynchus mykiss). The fish were obtained as swim-up fry from Mt. Lassen Trout Farm, Red Bluff, CA. The fish were from the same source, year class, the average length was 23 mm, and the average weight was 0.13 grams. The loading rate was 0.16 g fish/L of test water.

EXPOSURE PERIOD: 96 hours

STATISTICAL METHODS: The LC50 was determined using the computer program of C.E. Stephen (1978). The program calculates the LC50 and the 95% C.I. using probit analysis, the moving average method or binomial probability with nonlinear interpolation. The binomial method was used to evaluate mortality at 48, 72 and 96 hours

ANALYTICAL MEASUREMENTS: Oxygen concentration, pH, temperature, conductivity, hardness and alkalinity were measured throughout the test. Dissolved oxygen concentration was 6.1 to 8.1 mg O2/L, pH was 8.1-8.5, and temperature was 12 -12.5 degrees C. The conductivity, hardness and alkalinity of the dilution water were 280 umhos/cm, 140 mg/L as CaCO3, and 184 mg/L as CaCO3, respectively.

TEST CONCENTRATIONS: There were 5 nominal concentrations selected: 1, 1.7, 2.9, 4.8 and 8 mg/L; measured concentrations were 1.3, 1.9, 2.9, 4.6 and 7.7 mg/L; a negative control was also used. Test solutions were prepared by directly fortifying methyl bromide into aerated well water on a weight basis. The methyl bromide gas was bubbled into the water through a gas-tight syringe needle. The test solutions were allowed to equilibrate for approximately 2 hours; 2 ml were then removed and analyzed.

TEST DETAILS: The test was performed as a semi-static test. Test chambers were 4L serum bottles that were sealed to prevent volatilization of methyl bromide. The water used was freshwater obtained from a well 45 feet deep located on the test facility property. It is characterized as medium-hard water. The well water was filtered to remove particles and microorganisms. A photoperiod of 16 hours light and 8 hours dark was employed. Light intensity was 377 lux at the water surface.

After the methyl bromide gas was bubbled into the water through a gas-tight syringe needle, equilibrated for approximately 2 hours and then removed analyzed, the fish were introduced gradually into the test chambers. There were 5 trout per each of 4 chambers per concentration, totaling 20 trout per test concentration. Water quality criteria described above were measured throughout the test. All fish were observed for mortality and clinical signs of toxicity or abnormal behavior. These

observations were performed at 14, 24, 48, 72 and 96 hours after test initiation.

Result : RESULT: The LC50 (96 h) calculated was 3.9 mg/l with 95% confidence limits of 2.9 and 4.6 mg/l. Mortalities occurred at 4.6 mg/L at 48 hours (85% mortality). There was 100% mortality in 48 hours at 7.7 mg/L. Adverse behavioral effects observed included: lethargy, discoloration, loss of equilibrium, and lying on side w ith only gill movement. The no observed effect concentration (NOEC) is approximately 1.9 mg/l.

Test substance : TEST MATERIAL: Methyl bromide, 99.87% pure.

Attached document : AF1ResultsTable.doc

Reliability : (1) valid without restriction
DATA QUALITY: Study was conducted in accordance with a recognized scientific method for measuriing the acute toxicity of methyl bromide to fish. There was no mortality in the control group and the oxygen concentration was >60%. Water quality criteria were determined. The actual concentration of test material in the test chambers solutions was measured and supports the findings in the study.

26.12.2002 (5)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : static

Species : other: Daphnia magna (Cladoceran)

Exposure period : 48 hour(s)

Unit : mg/l

Analytical monitoring : yes

Method : other: FIFRA Subdivision E, Series 72-2, and is comparable to OECD Test Guideline 202 and EEC Directives.

Year : 1993

GLP : yes

Test substance : other TS: Methyl Bromide

Method : SPECIES: Daphnia magna. Daphnia neonates were less than 24 hours old and were obtained from cultures maintained at the testing facility. Adult daphnids in cultures were held for 21 days prior to collection of the juveniles for testing. The progeny from 3 or more adults were used in the test. During the 14 day holding period preceding the test, water temperatures ranged from 20 - 20.8 degrees C, pH was 8.2 - 8.9 and dissolved oxygen was 7.4 - 8.4 mg/L.

STATISTICAL METHODS: The LC50 was determined using the computer program of C.E. Stephen (1978). The program calculates the LC50 and the 95% C.I. using probit analysis, the moving average method or binomial probability with nonlinear interpolation. The binomial method was used to evaluate mortality at 24 and 48 hours

ANALYTICAL MEASUREMENTS: Oxygen concentration, pH, temperature, conductivity, hardness and alkalinity were measured throughout the test. Dissolved oxygen concentration was 8.0 to 8.6 mg O2/L, pH was 8.5 -8.6, and temperature was 20.1 -21.4 degrees C. The conductivity, hardness and alkalinity of the dilution water were 340 umhos/cm, 140 mg/L as CaCO3, and 186 mg/L as CaCO3, respectively.

TEST CONCENTRATIONS: There were 5 nominal concentrations selected: 1.3, 2.2, 3.6, 6.0 and 10 mg/L; measured concentrations were 1.2, 2.2, 3.5, 5.8 and 9.8 mg/L; a negative control was also used. Test solutions were prepared by directly fortifying methyl bromide into aerated well water on a weight basis. There were 20 daphnids per test concentration. The measured concentrations were the mean measured concentrations sampled at the initiation and termination of the study, and

averaged.

TEST DETAILS: The test was performed as a static test. Test chambers were nominally 100 mL serum bottles containing approximately 125 mL of test solution (no headspace) and sealed to prevent volatilization of methyl bromide. The water used was freshwater obtained from a well 45 feet deep located on the test facility property. It is characterized as medium-hard water. The well water was filtered to remove particles and microorganisms. A photoperiod of 16 hours light and 8 hours dark was employed. Light intensity was 968 lux at the water surface.

After the methyl bromide gas was bubbled into the water through a gas-tight syringe needle, equilibrated for approximately 2 hours and then removed and analyzed, the daphnids were introduced gradually into the test chambers. There were 5 daphnids per each of 4 chambers per concentration, totaling 20 individuals per test concentration. Water quality criteria described above were measured throughout the test. All daphnids were observed for mortality and clinical signs of toxicity or abnormal behavior. These observations were performed at 2, 24 and 48 hours after test initiation. The no mortality/no immobility concentration was determined by inspection.

Result : RESULTS: The 48 hour EC50 was 2.6 mg/L, with 95% confidence limits between 2.2 and 3.5 mg/L. The 48 hour no mortality/no immobility concentration was 1.2 mg/L. Daphnids in the negative control and low dose groups were normal. Mortalities occurred at 2.2 mg/L at 48 hours (15% mortality/immobility). There was 100% mortality in 48 hours at 3.5 and 5.8 mg/L. There was 100% mortality in 24 hours at 9.8 mg/L. Immobility was observed at 2.2 mg/L in 48 hours and at 5.8 mg/L in 24 hours. Mortality in the highest dose group prevented this from being observed. The no observed effect concentration (NOEC) is approximately 1.2 mg/l.

Test substance : TEST MATERIAL: Methyl bromide, 99.87% pure.

Attached document : AINV1ResultsTable.doc

Reliability : (1) valid without restriction
DATA QUALITY: Study was conducted in accordance with a recognized scientific method for measuring the acute toxicity of methyl bromide to daphnia. There was no mortality in the control group and the oxygen concentration was >60%. Water quality criteria were determined. The actual concentration of test material in the test chambers solutions was measured and supports the findings in the study.

26.12.2002 (4)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

(1) Chemical Manufacturers Association, Methyl Bromide Panel. Hydrolysis of Methyl Bromide. TESTING FACILITY: Bolsa Research Associates, Inc., Hollister, CA. STUDY NUMBER: BR289.1:93. DATE of REPORT: March 4, 1993. AUTHORS: Henry Lee, Ph.D.

(2) Chemical Manufacturers Association, Methyl Bromide Panel. Photohydrolysis of Methyl Bromide. TESTING FACILITY: Bolsa Research Associates, Inc., Hollister, CA. STUDY NUMBER: BR289.1:93. DATE of REPORT: March 4, 1993. AUTHORS: Henry Lee, Ph.D.

(3) The Methyl Bromide Industry Panel, CMA. Aerobic and Anaerobic Soil Metabolism of Methyl Bromide. TESTING FACILITY: Radian Corporation, Austin, TX. STUDY NUMBER: 266-040. DATE OF REPORT: September 23, 1988. AUTHOR: Larry D. Ogle.

(4) The Methyl Bromide Industry Panel, CMA. Methyl Bromide: A 48-Hour Static Acute Toxicity Test With the Cladoceran (Daphnia magna). TESTING FACILITY: Wildlife International Ltd., Easton , MD. STUDY NUMBER: Project Number 264A-102B. STUDY DATE: September 16, 1993. AUTHOR: Kurt R. Drottar and James P. Swigert, Ph.D.

(5) The Methyl Bromide Industry Panel, CMA. Methyl Bromide: A 96-Hour Static Acute Toxicity Test With The Rainbow Trout (Oncorhynchus mykiss). TESTING FACILITY: Wildlife International Ltd., Easton , MD. STUDY NUMBER: Project Number 264A-105A. STUDY DATE: December 16, 1993. AUTHOR: Kurt R. Drottar and James P. Swigert, Ph.D.